

REMARKS

Prior to the entry of the present amendment, claims 1-13 and 15-20 were pending in the present application. Claims 9-13 and 20 had been withdrawn from consideration and are hereby cancelled without prejudice. Claims 1-8 are also cancelled without prejudice. Applicants expressly reserve the right to pursue the cancelled subject matter in a timely filed continuation or divisional application. The amendments are presented in response to issues raised in the final Office Action, and are respectfully submitted to place the application in condition for allowance or, in the alternative, to reduce the issues upon appeal. Accordingly, entry of the amendment submitted herewith is respectfully requested.

In view of the foregoing amendments and the following remarks, reconsideration and favorable action on the pending claims are requested.

I. Claim Rejections Under 35 U.S.C. § 103

Claims 1-8 and Claims 15-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over a scientific abstract authored by Matsumoto, *et al* and published in 2000 ("Matsumoto 2000") or a scientific abstract authored by Matsumoto, *et al* and published in 2001 ("Matsumoto 2001"), in view of U.S. Patent Application Publication No. 2001/0006948 by Kang, *et al* ("Kang") and if necessary, in view of U.S. Patent No. 6,451,060 issued to Masuda, *et al* ("Masuda"). In addition, claims 1-8 and 15-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Masuda in view of Matsumoto 2000 or Matsumoto 2001 and Kang. As stated in § 2143 of the M.P.E.P.,

[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claims 1-8 have been cancelled without prejudice, rendering the rejection of these claims moot. With respect to claims 15-19, however, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and traverse the rejection of these claims.

The present invention provides a method for the surgical repair of intervertebral disc damage. Claim 15, from which claims 16-19 depend, recites that the surgical method comprises the steps of “producing a transplantable intervertebral disc tissue” and “implanting the intervertebral disc tissue into an intervertebral disc defect.” Surgical implantation is discussed throughout the specification, particularly in paragraphs 31 and 32. Furthermore, Example 3 describes in great detail the production of transplantable intervertebral disc tissue, selection of tissue for implantation, surgical implantation of the tissue into a disc defect, and assessment of the integration of the tissue after implantation.

In contrast, Matsumoto 2000 and Matsumoto 2001 neither expressly teach a method for the surgical repair of disc damage nor do they provide a basis for the reasonable expectation of success of such surgery. The Examiner asserts that these references “disclose producing engineered intervertebral disc tissue for implanting.” The references do not, however, disclose steps involving the actual implantation of engineered tissue into an intervertebral disc defect. In fact, the more recent reference, Matsumoto 2001, explicitly concludes, “It remains to be determined if such tissues can be transplanted *in vivo* to repair IVD defects and/or degeneration.” This statement clearly shows that the success of a surgical treatment using engineered disc tissue was uncertain to those of skill in the art. Applicants respectfully submit that the Examiner has not shown that, aside from the disclosure of the present invention, there was any reasonable expectation of success for the surgical repair of disc damage using engineered intervertebral disc tissue.

Similarly, the disclosures of Kang and Masuda both fail to teach the implantation of engineered disc tissue and fail to demonstrate a reasonable expectation of success for the surgical repair of disc damage using implanted tissue. Kang is directed to methods for introducing genes into intervertebral disc cells. Although an objective is the treatment of degenerative disc disease, Kang generally teaches away from treatments involving surgery. Kang notes that current

treatments are “generally highly invasive, and usually [require] surgery in which all or portions of the affected intervertebral disc or discs are removed.” Paragraph 7. Kang goes on to provide “methods for treating patients having degenerative disc disease, wherein such methods of treatment are generally non-invasive.” Paragraph 18. In another paragraph, Kang only suggests that support devices may be inserted into a patient’s disc for the purpose of providing exogenous genes, rather than to repair disc defects using engineered tissue. Paragraph 58. Finally, Masuda teaches a surgical method, but only for the repair of cartilage damage using cartilage matrix engineered from chondrogenic cells. Nothing in Masuda suggests an expectation that surgical implantation of engineered disc tissue will successfully repair intervertebral disc damage.

Because the cited references neither teach or suggest the claimed method and because there is no reasonable expectation of success for the surgical repair of intervertebral disc damage using engineered disc tissue, the cited references fail to establish a *prima facie* case of obviousness. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 15-19 under 35 U.S.C. § 103(a).

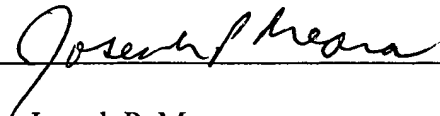
II. Conclusion

For the foregoing reasons, Applicants respectfully submit that the application is now in a condition for allowance. Consequently, Applicants respectfully request the Examiner withdraw the rejection of claims 15-19 and allow the application to issue. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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FOLEY & LARDNER LLP
 Customer Number: 23524
 Telephone: (608) 258-4303
 Facsimile: (608) 258-4258

By 
 Joseph P. Meara
 Attorney for Applicant
 Registration No. 44,932